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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,205	10/29/2001	Richard Anthony Godwin Smith	00486-8005.US00	2596

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
12/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jisacson@perkinscoie.com
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patentprocurement@perkinscoie.com

Office Action Summary	Application No.	Applicant(s)	
	09/936,205	SMITH ET AL.	
	Examiner	Art Unit	
	HOPE A. ROBINSON	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 9, 2009 has been entered.

Claim Disposition

2. Claims 9 and 19-21 are pending and under examination.

Specification

3. The specification is objected to because of the following informalities:

The specification is objected to because the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "A Method of Preparing an Organ by Perfusion".

Information Disclosure Statement

4. The Information Disclosure Statement filed on November 9, 2009 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Objection

5. Claim 9 is objected to because of the following informalities:

Claim 9 is objected to because item II has an extraneous period.

Claim 9 is objected to because the word 'complement' is misspelled as "compliment".

For clarity and precision of claim language it is suggested that the claim is amended to read,

"(Currently Amended) A method for preparing an organ by perfusion prior to transplantation or storage of the organ comprising:

(I) providing an ischemic reperfusion injury prevention preparation for perfusion of an organ prior to transplantation or storage of the organ, wherein the ischemic reperfusion injury prevention preparation comprises:

(A) a soluble [[derivative of a soluble]] polypeptide, that [[wherein the soluble derivative]] consists of:

a fragment of complement receptor 1 (CR1) conjugated to myristoyl and a basic amino acid sequence, wherein said fragment has [[having compliment]] complement inhibitory activity, [[and is]] wherein the soluble [[derivative]] polypeptide is [[set forth in]] SEQ ID NO: 1, and wherein the CR1 fragment is [[set forth at positions]] amino acid residues 2-197 of SEQ ID NO:1 and the basic amino acid sequence is [[set forth at positions]] amino acid residues 199-215 of SEQ ID NO:1; and

(B) a physiologically acceptable and non-reducing flush storage solution, wherein the [[physiologically acceptable]] flush storage solution is a kidney perfusion solution, that comprises potassium citrate, sodium citrate, mannitol, and magnesium sulphate; and

(II) perfusing the organ with the ischemic reperfusion injury prevention preparation, wherein the organ contains the ischemic reperfusion injury prevention preparation while isolated and prior to implantation, and the ischemic reperfusion injury prevention preparation retains the complement inhibitory activity of the soluble [[derivative.]] polypeptide.

Correction is required.

Maintained-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 9 and 19-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (U.S. 6,713,606 B1) in view of the Baxter SOLTRAN solution product #FKB4708G and Varty et al.,(BMJ 1994, volume 308, page 575).

Smith et al. teach CR1 fragments that would inherently include a fragment of CR1-3. Further, Smith et al. teach soluble CR1 polypeptide that is derivatized with a myristoyl group (See column 17, line 55). At column 18, Smith et al. teach the use of peptides for Post-Ischemic Reperfusion Conditions. Smith et al. does not specifically teach SOLTRAN solution.

As supporting evidence to the fact that SOLTRAN is a popular and widely used solution that is used as physiologically acceptable flush solution, examiner included in the instant office action a copy of the Baxter's product that is sold as SOLTRAN solution and is commonly used in perfusion procedures.

Varty et al. teach that SOLTRAN produced by Baxter company was used in perfusion for organ donation purposes. (See third paragraph of the Abstract, on page 575 as included).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method for preparing an organ by perfusion prior to transplantation or storage of the organ that uses soluble CR1 polypeptide which includes a CR1-3 fragment that is derivatized with a myristoyl group and to administer such peptides to a patient or a transplant prior to implantation as taught by Smith et al. and to use in such a method the SOLTRAN product that is commonly used as a physiologically acceptable flush solution used in perfusion procedures as taught by Varty et al. One skilled in the art would be motivated to design such a method when SOLTRAN is utilized because such physiological solutions are commonly used in transplanting of different organs and preventing rejection of such organs. Therefore, the invention is *prima facie* obvious.

Response to Arguments

7. Applicant's arguments have been considered in full, however, are not persuasive. Applicants cites *KSR* and *Eisai Co.*; and argue that "when claims are directed to chemical entities, the inquiry turns to similarities and differences between the claimed subject matter and those of the prior art'. It is further stated that the "examiner has focused on previous uses of SOLTRAN…The claimed invention is very different in that flush storage solution (i.e. SOLTRAN) is being used in an entirely different and non-

obvious context, namely as a delivery vehicle for the soluble derivative to be carried to where it is needed in the organ".

Firstly, applicant is arguing a limitation not present in the claims as the instant method is directed to preparing an organ by perfusion not a delivery vehicle as stated by applicants. Secondly, applicant's admit that SOLTRAN is an example of the claimed 'flush storage solution' which is in the art. SOLTRAN, is a physiologically acceptable flush solution that is routinely used during perfusion procedures and the name itself is trademarked. The art also discloses the claimed CR1. Thirdly, the Smith reference remains relevant because in column 19, lines 60-67, Smith et al. teach a method of delaying hyperacute allograft or hyperacute xenograft rejection in a human or non-human, which receives a transplant by administering an effective amount of a soluble complement inhibitor, such as soluble CR1 polypeptide and derivative, where such administration maybe to the patient or by application to the transplant prior to implantation. Therefore, Smith et al. teach administration of CR1 fragments or derivatives to patients before surgery or to the organs to be transplanted themselves (instant claims 19-21).

Moreover, the peptides or derivatives of Smith et al. are conjugated to myristoyl, as claimed in amended claim 9. In addition, the Supreme Court pointed out in *KSR*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR, 127 S. Ct. at 1741*. The Court thus reasoned that the analysis under 35 U.S.C. 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for

a court can take account of the "inferences and creative steps that a person of ordinary skill in the art would employ." *Id. at 1741*. The Court further advised that "[a] person of ordinary skill is…a person of ordinary creativity, not automation." *Id. at 1742*. Therefore, the claimed invention was obvious to make and use at the time the invention was made and was *prima facie* obvious.

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652